

## **REMARKS/ARGUMENTS**

### **Amendment to the Claims**

Claims 1-20 are currently in the application. Claims 1, 2, 5, 10, 11 and 20 are amended. Claim 16 is canceled. New Claim 21 is added.

Claims 1 and 10 are amended to correct the spelling of the term “intramuscular” (support at paragraph [0013]).

Claims 2 and 11 are amended to provide that the exerted pressure injects the injectable liquid at a substantially constant volumetric flow rate that effects a painless injection. (support at paragraph [0070]).

Claim 5 is amended to make express what is implicit in the claim.

Claim 20 is amended to correct grammar.

No new claims fees are believed due, and all claim amendments are fully supported by the specification as originally filed.

### **Rejections under 35 USC §103(a)**

A. Claims 1, 2, 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miskinyar (US 5527287) in view of Woehr et al. (US 20030144627)

Applicants traverse.

Rejections based on 35 U.S.C. § 103 must rest on a factual basis. In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 177-78 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968). In making such a rejection, the Examiner has the initial duty of supplying the requisite factual basis and may not, because of doubts that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis. Obviousness is a question of law based on underlying factual inquiries. The factual inquiries include:

- (A) determine the scope and contents of the prior art; and
- (B) ascertaining the differences between the claimed invention and the prior art.

a. The rejection fails because the factual characterization of the prior art is incorrect.

In the present case, the Examiner’s characterization of the prior art is factually incorrect,

and on that basis alone, the rejection fails to state the *prima facie* obviousness requirement.

At the outset, the Examiner's finding that Miskinyar discloses a manually-powered injection device is factually incorrect. The only powering or force-applying means shown and described are pre-compressed springs (e.g., element 70, Fig. 2, element 184 in Fig. 10, and element 256, Fig. 12) and chambers filled with compressed gas (e.g., element 43, Fig. 2). There are no power or needle insertion means shown or described by Miskinyar that are powered manually, by hand.

The Examiner's finding that Miskinyar discloses a device for painless intramuscular injection is inaccurate. The terms "pain" and "painless" are not mentioned or suggested in Miskinyar. A person of ordinary skill in the art would expect that intramuscular injections are painful unless expressly stated otherwise. The range of needle sizes in terms of diameter or gauge disclosed by Miskinyar does not inherently provide for painless needle insertion into the skin. There is not described or suggested in Miskinyar the problem of pain caused by the typical rapid injection intramuscularly of vaccines. There is no description or suggestion of a rate of vaccine injection that would inherently result in painless intramuscular injection (as provided in Applicants' Claim 21).

The range of needle lengths that are sufficient for intramuscular needle insertion is shown in only one embodiment of Miskinyar, Fig. 10, which is a "pen-style" hand-held injection device. In this embodiment, there is not shown or described any means for semi-permanently attaching the device to the skin of a person, which a person of ordinary skill would not expect since the device is obviously for hand-held use. Consequently, none of the diverse embodiments described by Miskinyar provide a device that has a base for semi-permanent attachment to the skin for intramuscular needle insertion and injection.

Woehr et al. disclose a list of the international standards for push and pull strengths that a needle and hub must provide based on a needle's outer diameter (Table 1). The needle sizes described in Table 1 do not inherently provide for painless needle insertion into the skin across the full range of sizes. A few of the sizes may, but most do not. For the record, Woehr et al. teaches a unique hypodermic needle assembly having a needle shield that can be retracted from blocking the hypodermic needle tip. Woehr et al. do not describe expressly the use of any particular needle size, and provide no teaching or suggestion of the problem of pain caused by the use of larger-diameter sized needles during intramuscular needle insertion. Consequently,

while it may be possible that the device of Miskinyar could be modified by using one of the needles of any size shown in the Table 1 of Woehr et al., such mere possibility does not make the modification obvious unless the prior art suggested the desirability of the modification (*see In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984)). Neither Miskinyar nor Woehr et al. recognize, discuss or would suggest the benefit of a painless needle insertion, involving the appropriately sized needle defined by Applicants.

b. The rejection fails to provide a rational basis to combine the teachings of the references.

“Rejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR*, 550 U.S. at \_\_\_, 82 USPQ2d at 1396 quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). The rejection states that it would be obvious to modify Miskinyar with the smaller-diameter needles of Woehr et al. “for the purpose of providing a needle of sufficiently sized diameter to require an appropriate application of strength for use”. The Push and Pull strengths in Table 1 of Woehr et al. describe the international standards for the minimum strength from physical separation of a needle from its hub. The rationale provided by the Examiner, as motivation for combining the two references, is unclear and cannot be understood. Without a rationale basis, the mere conclusion that it would be obvious to combine a selected feature in Woehr et al. into the device of Miskinyar is not sufficient to establish a *prima facie* case of obviousness. Some objective reason to combine the teachings of the references is required. (“A statement that modifications of the prior art to meet the claimed invention would have been 'well within the ordinary skill of the art at the time the claimed invention was made' because the references relied upon teach that all aspects of the claimed invention were individually known in the art, is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references.” *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993).)

c. The rejection employs hindsight to combine specifically selected features from the teachings of the references.

To a person of ordinary skill in the art, Woehr et al. teach a unique hypodermic needle

assembly having a needle shield that can be retracted from blocking the hypodermic needle tip. The Examiner has inappropriately taken just one feature (the Push and Pull strength values for a broad range of needle sizes) from the teaching of an otherwise unique needle assembly, and attempts to modify Miskinyar with that single feature only. The law requires that the disclosures be combined based on the overall teaching of the references, and cannot select isolated features from the prior art to combine without some motivation provided by the references. The only motivation in the record for a person of ordinary skill to select the isolated feature (needle size) from Woehr et al. to combine with Miskinyar is Applicants' invention, which amounts to impermissible hindsight.

Furthermore, if a person of ordinary skill were to attempt to combine the unique hypodermic needle assembly of Woehr et al., with the device of Miskinyar, the resulting product design and function would be unpredictable, and not obviously functional. Just how would one configure and activate the needle guard assembly 16 and the spring clip 20 prior to extending out to the tip of the needle? It is not immediately obvious.

Finally, in terms of Applicants' new Claim 21, which provides for specific liquid flow rates to effect a painless injection of the injectable liquid, neither Miskinyar nor Woehr et al. recognize, discuss or would suggest the benefit of a painless intramuscular injection, involving the appropriately-configured injection means for constant volumetric delivery of the liquid painlessly.

For that matter, none of the prior art of record discloses the problem of pain associated with intramuscular vaccines and liquid injections, and the means for both a painless needle insertion into the muscle and a painless injection of the vaccine.

B. Claims 3-8 and 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miskinyar in view of Woehr et al., and further in view of McWethy et al. (US 7004929).

(1) Claims 4, 5, 6, 13, 14 and 15:

In formulating a rejection under Miskinyar and Woehr et al. in view of McWethy, the Examiner has prefaced the combination by asserting that Miskinyar in view of Woehr et al. make obvious Claims 4, 5, 6, 13, 14 and 15, which is the previous rejection above. Clarification is

requested. The Examiner's failure to clearly address each claim independently and expressly makes responding to the rejection burdensome and complex.

The Examiner implies that Claims 4 and 13, which provide a means for retracting the injection needle after its insertion, are obvious over Miskinyar in view of Woehr et al. The Examiner alleges that the combination "discloses the apparatus as claimed, including means for retracting the injection needle (spring 102, fig. 8), whereby the injection end of the needle can be retracted from its second position to a third position wherein the injection end of the needle is within the housing".

Applicant traverses.

Neither Miskinyar nor Woehr et al. disclose a "retracting means" as claimed. Miskinyar mentions the needle in a "retraction position" within the housing, but this position is prior to its insertion of the needle into the patient (Fig. 10 item 152, and col 5 line 50, and Fig 8 item 102). It is the "starting" position of the device. The "retraction position" of Miskinyar is unrelated to a "retracting means" or the third position of the needle of Applicants' invention. Miskinyar provides that "(t)he resilient bias of the retraction spring 102 is designed to be less than the force required for slidably advancing the piston 100 in the ampoule chamber 96, 30 thereby ensuring that the medication is not prematurely rejected from the ampoule chamber" (col 5 lines 28-31)." Miskinyar addresses the concern of the exposed needle after injection, by placing the cover 38 over the base, as shown in Fig. 7 (col 4 line 35-38).

The Examiner also implies that Claims 5 and 14, which provide axial movement of the needle carriage in response to a manual force, are obvious over Miskinyar in view of Woehr et al.

Applicants traverse.

The Examiner's assertion that Miskinyar in view of Woehr et al. discloses axial movement of the needle "in response to a manual force by a person", is factually incorrect. There is no power, force or needle insertion means shown or described by Miskinyar or Woehr et al. that moves the injection needle manually, by hand.

The Examiner also implies that Claims 6 and 15, which provide an implement for use in applying the manual force to the needle carriage, are obvious over Miskinyar in view of Woehr

et al.

Applicants traverse.

The implement of the Claims 6 and 15 is described as a plunger or stem that can be used in place of the finger or hand to apply the manual insertion force to the needle carriage (paragraph [0016]). The manual insertion force is that force that moves the needle carriage from its first position to the second position for insertion of the needle intramuscularly.

The Examiner implies that the button 104 of Figs. 8 and 9 of Miskinyar is such an implement, but this is factually incorrect. According to Miskinyar, “(t)he patient presses on the actuator button 104 sufficiently to override the resilient detent of the circular clip washer 116. This permits the actuator spring 128 to be released, forcing the ampoule chamber 96 outwardly into its extended position, which is shown in FIG. 9.” (emphasis added). Clearly, the force that moves the ampoule chamber and the needle therewith to its extended position is provided by the pre-compressed actuator spring 128, which neither delivers a manual force, nor applies the force through the implement. The depressing of the button activates the spring force but does not manually move the needle.

Therefore, the rejection of Claims 4, 5, 6, 13, 14 and 15 fails to establish *prima facie* obviousness, because the factual characterizations of the prior art are incorrect, and the alleged combination fails to disclose each element and feature of the Claims.

(2) Claims 3, 7-8, 12, and 16-17

In addition to the shortcomings of the base rejection of Miskinyar in view of Woehr et al., addressed above, the combination further in view of McWethy further fails to establish *prima facie* obviousness.

The rejection first states that the references Miskinyar and Woehr et al. fail to teach the respective features of Claims 3 and 12, Claims 7 and 16, and Claims 8 and 17, and continues by reciting the text of these Claims essentially verbatim. Then the rejection continues by stating what McWethy teaches, but then again only repeats verbatim the same text from Applicant's Claims, though adding figure references and text passages from McWethy in parentheses. Finally, the rejection concludes that it would have been obvious to modify Miskinyar in view of Woehr et al. to provide (once again) the text of the rejected Claim, essentially verbatim.

Applicants traverse.

a. The rejection of Claims 3, 7-8, 12, and 16-17 fails because the rejection failed to ascertain the scope of the prior art.

The Examiner has not characterized or construed the scope of the McWethy reference, and as such has factually mischaracterized the prior art. The rejection does no more than point at a paragraph or figure in the art, and then expects Applicants to construct the specifics of the rejection in order to make a response. A *prima facie* rejection requires more.

With regard to Claims 3 and 12, the needle insertion securement of Applicants' invention is described in paragraph [0123] as retaining the needle carriage, and the injection needle, in the second inserted position extending from the base of the housing, after the needle has been moved manually to the second inserted position (Claim 1, b)). The rejection simply refers to a complicated syringe assembly in Figure 4 of McWethy, identifies retaining arms 26 and latches 27, a needle, a syringe cylinder and plunger, and numerous other elements.

With regard to Claim 7 (Claim 16 is canceled), related to a needle insertion securement, the Examiner simply points to column 5 lines 48-67 of McWethy. The Examiner does not provide a rational explanation of why those 20 lines of text makes obvious how the retaining arms 26 and latches 27 are to associate with the features of Miskinyar and Woehr et al. to make Applicants' claimed invention.

With regard to Claims 8 and 17, related to the retracting means comprising a disengagement means and a power means, the Examiner merely points to Fig. 5 and to item 46 as a disengagement means, and item 24 as a power means. No explanation has been provided for how these features are to be associated with the device of Miskinyar and Woehr et al.

In all of the rejections of Claims 3, 7-8, 12, and 16-17, the Examiner fails to make a rationale explanation of why a person of ordinary skill would find the claims *prima facie* obvious over the combination of references and features.

b. The rejection of Claims 3, 7-8, 12, and 16-17 fails to show that the alleged combination of the prior art to obtain the Claims is predictable.

First, it is not obvious or evident to a person of skill in the art that the inserted needle and carriage in Miskinyar requires a means for securing the needle or carriage in the inserted position. In all embodiments of Miskinyar, the pre-loaded biasing spring overwhelms the much

weaker retraction spring upon activation; there is no need for retaining the needle in the inserted position.

Second, it is not predictable or immediately obvious how the alleged features 26 and 27, and 24 and 46 of McWethy are to be configured within the device disclosed in Miskinyar in view of Woehr et al., or how Miskinyar in view of Woehr et al. are to be modified to provide these features. The rejection should explain a predictable combination of the teaching of the three references to disclose Applicants' claimed invention, and not simply the identification of an isolated feature in a reference that may satisfy the literal requirements of the claim within its own reference, but has not, and cannot, be shown to be combined predictably with or modified into the other two references.

C. Claims 9 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miskinyar in view of Woehr et al., and further in view of Flaherty (US 6749587).

Applicants traverse.

The rejection fails because the factual characterization of the prior art is incorrect.

The rejection alleges that Miskinyar in view of Woehr et al. provides a base comprising an adhesive, and that Flaherty teaches a separable base and base securement means. However, Flaherty describes a reusable assembly 700 and a disposable assembly 800 of a drug infusion device. The disposable assembly 800 of Flaherty includes a housing, a reservoir 30 and the needle 70. While the disposable assembly 800 is separable from the reusable assembly 700, the disposable assembly 800 of Flaherty is not a separable base.

As the Examiner's characterization of the prior art is factually incorrect, the Examiner has not properly ascertained in writing the scope of the prior art. Furthermore, since Flaherty does not disclose a separable base that is separable from the housing, the rejection cannot teach each element and feature of the Claims, and fails to establish the *prima facie* obviousness requirements.

D. Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miskinyar in view of Woehr et al. and McWethy, and further in view of Landau (US 6264629).

Applicants traverse.

The rejection fails because the factual characterization of the prior art is incorrect.



The rejection alleges that Landau teaches cooperating threads between a carriage and reservoir, a penetrable membrane of the reservoir, and a piercing conduit 80. But, Landau teaches a needle-less hypodermic jet injection apparatus – no needle, no needle carriage moving between positions, and no piercing conduit in liquid communication. The alleged piercing conduit 80 is associated with the compressed gas cylinder, and is completely unrelated to the features required in Applicants' claims.

A factually incorrect characterization of the prior art cannot support a proper written determination of the scope of the prior art. And, since Landau does not disclose several required elements and features of the claims, the rejection *per se* fails to establish the *prima facie* obviousness.

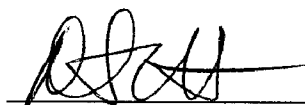
### Conclusion

Applicants believe a complete response to the office action has been provided, and that the present invention as claimed clearly distinguishes the teachings of the prior art of record. Applicants request a prompt allowance of all claims.

Respectfully submitted,

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